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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/200,791	11/30/1998	THOMAS M. BEHR	018734/0161	9799

26633 7590 06/07/2005

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EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/200,791

**Applicant(s)**

BEHR ET AL.

**Examiner**

Larry R. Helms

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-21, 23-29 and 31-43 is/are pending in the application.
- 4a) Of the above claim(s) 42 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-21, 23-29 and 31-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

1. Claims 1-9, 11-21, 23-29, 31-43 are pending.

Claims 38, 40 have been amended. It is noted that claim 19 has been amended but does not indicate the material removed from the claim. The listing of the claims as filed with the amendment of 3/31/05 will be treated as the claims under examination.

Claims 42-43 have been added.

2. Newly submitted claims 42-43 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 42-43 recite a method of increasing the dosage of a protein conjugate comprising a 2-3 fold increase is relative to the protein conjugate in the absence of a compound. The added claim methods are distinct from those originally examined because of different method objectives and method steps. The added claims require comparing a conjugate with a added compound to a conjugate without a compound. The original claims did not require such and were to methods of reducing kidney retention of a protein conjugate.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 42-43 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Claims 1-9, 11-21, 23-29, 31-41 are under examination.

4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

***Rejections Withdrawn***

5. The rejection of claim 38 under 35 U.S.C. 112, first paragraph is withdrawn in view of the amendment to the claim.

6. The rejection of claims 19 and 38 under 35 U.S.C. 112, first paragraph is withdrawn in view of the amendment to the claims.

7. The rejection of claims 19, 38, and 40 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

***Response to Arguments***

***Priority***

8. The instant application is a CIP of 08/407899 filed 3/21/95 (now US Patent 5,843,894). The claims in the instant application recite the limitation of a method of reducing kidney retention of a protein conjugate. This limitation is not seen in the

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08/407899 application. The 08/407899 application is directed to reducing renal uptake of antibody and antibody fragment conjugates which is a species of the now claimed genus of protein conjugates. The species of antibodies does not support the genus of just any protein conjugate. In addition, the glycoprotein conjugates and lipoprotein conjugates do not have support in the 08/407899 application (see claim 2 in the instant application). As such the claims are granted the priority date of the instant application, 11/30/98.

The response filed 3/21/05 has been carefully considered but is deemed not to be persuasive. The response states a textbook example about widgets (see page 10 of response). In response to this argument, it is unclear what this argument has to do with the priority because the widget case was about a CIP and a sale of widgets. It is unclear to the examiner what the discussion is or has to do with the instant case.

The response states that column 1, lines 33-36 in the patent '894 has support for the claims in that it recites the problem to be addressed in the patent and that the proteins are not greater than about 60 kD and thus the claimed proteins are those described in the parent application and such proteins are antibody fragments in the '894 application and any other protein conjugate in the present application (see page 10-11 of the response). In response to this argument, while the '894 patent does recite how the renal uptake of proteins smaller than 60 kD occur, there is no contemplation other than antibody fragment conjugates as the protein conjugates. In fact the '894 patent teaches "This invention relates to a method for reducing renal uptake of monoclonal antibody fragments" (see column 1, lines 1-6) and nowhere ever recites that the method

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could be used with just any protein conjugate. Thus, the claims in the instant application are granted the priority date of 11/30/98 as previously indicated.

9. The rejection of claims 1-8, 11-19, 23-28, 31-39, 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Behr et al (Cancer Research 55:3825-3834, 1995) is maintained.

The response states that the rejection is improper because the claims are afforded the priority date of the '894 application. In response to this argument, the claims are not granted this date and as such the rejection stands.

***Claim Rejections - 35 USC § 103***

10. The rejection of claims 1-9, 11-21, 23-29, 31-41 under 35 U.S.C. 103(a) as being unpatentable over Behr et al (Cancer Research 55:3825-3834, 1995), and further in view of Grey et al (U. S. Patent 5,380,513, issued 1/10/95, IDS #4) and Raines et al (U.S. Patent 5,840,296, filed 10/15/97) is maintained.

The response states that the rejection is improper because the claims are afforded the priority date of the '894 application. In response to this argument, the claims are not granted this date and as such the rejection stands.

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11. The rejection of claims 1-9, 11-21, 23-29, 31-41 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 38-47 of copending Application No. 10/438,219 is maintained.

The response filed 3/21/05 has been carefully considered but is deemed not to be persuasive. The response states that the rejection be set aside until allowable subject matter is received (see page 15 of response). In response to this argument, no claims are allowed and as such the rejection is maintained.

### ***Conclusion***

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew, can be reached at (571) 272-0787.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is 703-872-9306.

Larry R. Helms

571-272-0832

LARRY R. HELMS, PH.D  
PRIMARY EXAMINER

